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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
ROMEO, DAVID S	

ART UNIT	PAPER NUMBER
1647	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No.	Applicant(s)	
	10/580,901	SHARMA ET AL.	
	Examiner	Art Unit	
	David S. Romeo	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-23,28-33,39-53 and 55-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *3,7,11,19 and 20* is/are objected to.

8)☒ Claim(s) *1-3,5-23,28-33,39-53 and 55-66* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The complement of SEQ ID NO: 1, the complement of SEQ ID NO: 3, the reverse complement of SEQ ID NO: 1, the reverse complement of SEQ ID NO: 3, the reverse sequence of SEQ ID NO: 1 and the reverse sequence of SEQ ID NO: 3 (claim 3) could be infringed without infringing a polynucleotide encoding a polypeptide at least 95% identical to SEQ ID NO: 2 because the complement of SEQ ID NO: 1, the complement of SEQ ID NO: 3, the reverse complement of SEQ ID NO: 1, the reverse complement of SEQ ID NO: 3, the reverse sequence of SEQ ID NO: 1 and the reverse sequence of SEQ ID NO: 3 do not encode a polypeptide at least 95% identical to SEQ ID NO: 2.

Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A fusion polypeptide comprising a fragment of the polypeptide of claim 1 (claim 7) could be infringed without infringing the polypeptide of claim 1.

Claim 11 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the

claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A vector comprising a polynucleotide encoding a pp at least 95% identical to SEQ ID NO: 2 in the antisense orientation could be infringed without infringing a polynucleotide encoding a polypeptide at least 95% identical to SEQ ID NO: 2 (claim 2) or a conservatively substituted variant of SEQ ID NO: 2 (claim 5) in the sense orientation

Claims 19 and 20 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Myostatin (claim 19) or a myostatin mimetic (claim 20) could be infringed without infringing a compound capable of binding to the polynucleotides listed in claim 15 because myostatin does not bind to such polynucleotides.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 6, 7, 13 (in part) and 52, drawn to a polypeptide at least 95% identical to SEQ ID NO: 2.

Group II, claim(s) 2, 3 (in part), 5, 8–12, and 13 (in part), drawn to a polynucleotide encoding a polypeptide at least 95% identical to SEQ ID NO: 2.

Group III, claim(s) 3 (in part) and 13 (in part), drawn to the reverse complement of SEQ ID NO: 1 and the reverse sequence of SEQ ID NO: 1.

Group IV, claim(s) 3 (in part) and 13 (in part), drawn to the reverse complement of SEQ ID NO: 3 and the reverse sequence of SEQ ID NO: 3.

Group VI, claim(s) 13 (in part), drawn to SEQ ID NO: 5.

Group VII, claim(s) 13 (in part), drawn to the reverse complement of SEQ ID NO: 5.

Group VIII, claim(s) 13 (in part), drawn to an antisense polynucleotide of SEQ ID NO: 1.

Group IX, claim(s) 13 (in part), drawn to an antisense polynucleotide of SEQ ID NO: 3.

Group IX, claim(s) 13 (in part), drawn to an antisense polynucleotide of SEQ ID NO: 5.

Group X, claim(s) 15–18 (in part) and 23, drawn to a compound capable of binding a polynucleotide encoding SEQ ID NO: 2 or 4.

Group XI, claim(s) 15–18 (in part) and 23, drawn to a compound capable of binding the polynucleotide of SEQ ID NO: 5.

Group XII, claim(s) 15–18 and 23, drawn to a compound capable of binding the reverse complement of SEQ ID NO: 1 or 3.

Group XIII, claim(s) 19, drawn to myostatin.

Group XIV, claim(s) 20–22, drawn to myostatin mimetic.

Group XV, claim(s) 28 (in part) and 29–33, drawn to a method of regulating muscle growth comprising administering the polypeptide of SEQ ID NO: 2 or 4.

Group XVI, claim(s) 28 (in part) and 29–33, drawn to a method of regulating muscle growth comprising administering the polynucleotide of SEQ ID NO: 1 or 3.

Group XVII, claim(s) 28 (in part) and 29–33, drawn to a method of regulating muscle growth comprising administering the polynucleotide of SEQ ID NO: 5.

Group XVIII, claim(s) 28 (in part) and 29–33, drawn to a method of regulating muscle growth comprising administering the reverse complement of SEQ ID NO: 1.

Group XIX, claim(s) 28 (in part) and 29–33, drawn to a method of regulating muscle growth comprising administering the reverse sequence of SEQ ID NO: 1.

Group XX, claim(s) 28 (in part) and 29–33, drawn to a method of regulating muscle growth comprising administering the reverse complement of SEQ ID NO: 3.

Group XXI, claim(s) 28 (in part) and 29–33, drawn to a method of regulating muscle growth comprising administering the reverse sequence of SEQ ID NO: 3.

Group XXII, claim(s) 28 (in part) and 29–33, drawn to a method of regulating muscle growth comprising administering the polynucleotide of SEQ ID NO: 5.

Group XXIII, claim(s) 28 (in part) and 29–33, drawn to a method of regulating muscle growth comprising administering the reverse complement of SEQ ID NO: 5.

Group XXIV, claim(s) 28 (in part) and 29–33, drawn to a method of regulating muscle growth comprising administering an antisense polynucleotide of SEQ ID NO: 1.

Group XXV, claim(s) 28 (in part) and 29–33, drawn to a method of regulating muscle growth comprising administering an antisense polynucleotide of SEQ ID NO: 3.

Group XXVI, claim(s) 28 (in part) and 29–33, drawn to a method of regulating muscle growth comprising administering an antisense polynucleotide of SEQ ID NO: 5.

Group XXVII, claim(s) 28 (in part) and 29–33, drawn to a method of regulating muscle growth comprising administering a compound capable of binding a polynucleotide encoding SEQ ID NO: 2 or 4.

Group XXVIII, claim(s) 28 (in part) and 29–33, drawn to a method of regulating muscle growth comprising administering a compound capable of binding the polynucleotide of SEQ ID NO: 5.

Group XXIX, claim(s) 28 (in part) and 29–33, drawn to a method of regulating muscle growth comprising administering a compound capable of binding the reverse complement of SEQ ID NO: 5.

Group XXX, claim(s) 39–41, drawn to a transgenic animal comprising a vector comprising a polynucleotide encoding SEQ ID NO: 2 or 4.

Group XXXI, claim(s) 42 (in part), 43, 49 and 50, drawn to a method of predicting muscle mass comprising determining the amount of a polynucleotide of SEQ ID NO: 1 or 3.

Group XXXII, claim(s) 42 (in part), 44, 49 and 50, drawn to a method of predicting muscle mass comprising determining the amount of a polypeptide of SEQ ID NO: 2 or 4.

Group XXXIII, claim(s) 45 (in part) and 46–48, drawn to a method of detecting a variant of mighty polynucleotide using the polynucleotide of SEQ ID NO: 1 or 3.

Group XXXIV, claim(s) 45 (in part) and 46–48, drawn to a method of detecting a variant mighty polynucleotide using the polynucleotide of SEQ ID NO: 5.

Group XXXXV, claim(s) 45 (in part) and 46–48, drawn to a method of detecting a variant mighty polynucleotide using the reverse complement of SEQ ID NO: 1.

Group XXXXVI, claim(s) 45 (in part) and 46–48, drawn to a method of detecting a variant mighty polynucleotide using the reverse complement of SEQ ID NO: 3.

Group XXXXVII, claim(s) 45 (in part) and 46–48, drawn to a method of detecting a variant mighty polynucleotide using the reverse complement of SEQ ID NO: 5.

Group XXXVIII, claim(s) 51, drawn to an antibody that binds a polypeptide at least 95% identical to SEQ ID NO: 2.

Group XXXIX, claim(s) 53 and 55–58, drawn to a polynucleotide at least 95% identical to SEQ ID NO: 5.

Group XL, claim(s) 59–66, drawn to a method of expressing a desired protein in a cell using a polynucleotide at least 95% identical to SEQ ID NO: 5 linked to a reporter gene.

The inventions listed as Groups I–XL do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Each of the groups has a special technical feature that is either a polynucleotide at least 95% identical to SEQ ID NO: 3, a polynucleotide at least 95% identical to SEQ ID NO: 5 or a polypeptide at least 95% identical to 2. In order for the groups to have unity of invention it is necessary that the special technical feature be a contribution over the prior art. The documents in the international search report filed with the present application show that there is a presumption of lack of novelty or inventive step with respect to a polynucleotide at least 95% identical to SEQ ID NO: 3, a polynucleotide at least 95% identical to SEQ ID NO: 5 and a polypeptide at least 95% identical to 2. Therefore, the inventions of groups I–XL do not fulfill the requirements for unity of invention.

Moreover, SEQ ID NO: 5 and each of SEQ ID NO: 1 and 3 do not share a common structural feature and each functions dissimilarly. The reverse sequence and the reverse complement of SEQ ID NO: 1, 3 or 5 and SEQ ID NO: 1, 3 or 5 do not share a common structural feature and each functions dissimilarly.

Methods of using sense polynucleotides, the special technical feature of groups V and VI, are clearly different from methods of using antisense polynucleotides, the special technical feature of groups VII and VIII.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

muscular dystrophy, muscle cachexia, atrophy, hypertrophy, muscle wasting associated cancer, HIV, amyotrophic lateral sclerosis (ALS), diseases associated with cardiac muscle growth, promoting muscle regeneration after muscle injury.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

claims 28-33 correspond to the species.

The following claim(s) are generic: 28-33.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or

corresponding special technical features for the following reasons: Each of the species has a special technical feature that is either a polynucleotide at least 95% identical to SEQ ID NO: 3, a polynucleotide at least 95% identical to SEQ ID NO: 5 or a polypeptide at least 95% identical to 2. In order for the species to have unity of invention it is necessary that the special technical feature be a contribution over the prior art. The documents in the international search report filed with the present application show that there is a presumption of lack of novelty or inventive step with respect to a polynucleotide at least 95% identical to SEQ ID NO: 3, a polynucleotide at least 95% identical to SEQ ID NO: 5 and a polypeptide at least 95% identical to 2. Therefore, the species do not fulfill the requirements for unity of invention.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

sheep, cow, bull, deer, poultry, turkey, pig, horse, mouse, rat, fish and human.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: claims 42, 49, 50, 53, 62, 65, 66 correspond to the species.

The following claim(s) are generic: 42, 49, 50, 53, 62, 65, 66.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Each of the species has a special technical feature that is either a polynucleotide at least 95% identical to SEQ ID NO: 3, a polynucleotide at least 95% identical to SEQ ID NO: 5 or a polypeptide at least 95% identical to 2. In order for the species to have unity of invention it is necessary that the special technical feature be a contribution over the prior art. The documents in the international search report filed with the present application show that there is a presumption of lack of novelty or inventive step with respect to a polynucleotide at least 95% identical to SEQ ID NO: 3, a polynucleotide at least 95% identical to SEQ ID NO: 5 and a polypeptide at least 95% identical to 2. Therefore, the species do not fulfill the requirements for unity of invention..

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

green fluorescent protein, a red fluorescent protein, a luciferase enzyme, β-galactosidase enzyme.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

claims 53, 59, 61 correspond to the species.

The following claim(s) are generic: 53, 59, 61.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Each of the species has a special technical feature that is either a polynucleotide at least 95% identical to SEQ ID NO: 3, a polynucleotide at least 95% identical to SEQ ID NO: 5 or a polypeptide at least 95% identical to 2. In order for the species to have unity of invention it is necessary that the special technical feature be a contribution over the prior art. The documents in the international search report filed with the present application show that there is a presumption of lack of novelty or inventive step with respect to a polynucleotide at least 95% identical to SEQ ID NO: 3, a polynucleotide at least 95% identical to SEQ ID NO: 5 and a polypeptide at least 95% identical to 2. Therefore, the species do not fulfill the requirements for unity of invention..

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH

FRIDAY FROM 9:00 A.M. TO 5:30 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, MANJUNATH RAO, CAN BE REACHED AT (571)272-0939.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-8300.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING MAY BE OBTAINED FROM THE PATENT APPLICATION INFORMATION RETRIEVAL (PAIR) SYSTEM. STATUS INFORMATION FOR PUBLISHED APPLICATIONS MAY BE OBTAINED FROM EITHER PRIVATE PAIR OR PUBLIC PAIR. STATUS INFORMATION FOR UNPUBLISHED APPLICATIONS IS AVAILABLE THROUGH PRIVATE PAIR ONLY. FOR MORE INFORMATION ABOUT THE PAIR SYSTEM, SEE HTTP://PAIR-DIRECT.USPTO.GOV. CONTACT THE ELECTRONIC BUSINESS CENTER (EBC) AT 866-217-9197 (TOLL-FREE) FOR QUESTIONS ON ACCESS TO THE PRIVATE PAIR SYSTEM,

/DAVID S ROMEO/
PRIMARY EXAMINER, ART UNIT 1647

DSR
JUNE 30, 2009